AF

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/350,518	07/09/1999	JOHN C. REED	P-LJ-3578	8259

41552 7590 10/20/2005

MCDERMOTT, WILL & EMERY
4370 LA JOLLA VILLAGE DRIVE, SUITE 700
SAN DIEGO, CA 92122

EXAMINER	
SANG, HONG	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/350,518	REED, JOHN C.	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-14,16,20-27,32-34,36,37,44 and 50-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-14,16,20-27,32-34,36,37,44 and 50-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 July 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: Reed

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/8/2004 has been entered.

2. Claims 11-14, 16, 20-27, 32-34, 36-37, 44 and 50-66 are pending and under examination.

Claim Rejections Withdrawn

3. The rejection of claims 11-14, 16, 20-27, 32-34, 36-37, 44 and 50-66 under 35 U.S.C. 112, first paragraph, as not being enabled for determining the reference level is withdrawn in view of the reference provided by applicants and applicant's persuasive arguments filed on 10/8/2004.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 11, 13-14, 16, 21-22, 24-27, 32, 34, 36-37, 44 and 50-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print).

Claims are drawn to a method for prognosis of disease-free or overall survival of an individual having a breast cancer tumor, comprising determining, using a BAG-1 specific antibody, the level of BAG-1 protein expression in a sample of said tumor or tumor cells from a body fluid during stage I or stage II of said cancer, wherein a high level of BAG-1 expression relative to a reference level of BAG-1 expression correlates positively with disease-free or overall survival; A method for predicting the risk of tumor recurrence or spread in an individual having a breast cancer tumor, comprising determining, using a BAG-I specific antibody, the level of BAG-I protein expression in a sample of said tumor or breast tumor cells from a body fluid from said individual during stage I or stage II of said cancer, wherein a high level of BAG-I expression relative to a reference level of BAG-I expression correlates negatively with tumor recurrence or spread; A method for screening a breast cancer patient to determine the risk of tumor metastasis or chance of survival, said method comprising: (a) determining, using a BAG-I specific antibody, the level of expression of BAG-I protein in a cancerous tissue sample or tumor cells from a body fluid sample from said patient during stage I or stage 11 of said cancer; and (b) classifying a patient having high levels of expression of BAG-I

protein, relative to a reference level, as being less likely to suffer tumor metastasis or having an increased chance of survival; A method for determining the proper course of treatment for a patient suffering from breast cancer, said method comprising: (a) determining, using a BAG-I specific antibody, the level of BAG-I protein expression in a cancerous tissue sample or tumor cells from a body fluid from said patient during stage I or stage II of said cancer; (b) identifying a first group of patients having low levels of BAG-I expression relative to a reference level of BAG-I expression, which first group of patients may require treatment proper for patients having a lesser chance of survival or being more likely to suffer tumor recurrence or spread; and (c) identifying a second group of patients having high levels of BAG-I expression relative to a reference level of BAG-I expression, which second group of patients may require treatment proper for patients having a greater chance of survival and being less likely to suffer tumor recurrence or spread; A method for determining risk of tumor recurrence or spread in a patient suffering from breast cancer, said method comprising: (a) determining, using a BAG-I specific antibody, the level of expression of BAG-I protein in a cancerous tissue of a patient during stage I or stage 11 of said cancer; and (b) classifying said patient as belonging either to a first group of patients having high levels of expression of BAG-I relative to reference level of BAG-I expression, or a second group of patients having low levels of expression of BAG-I relative to a reference level of BAG-I expression, wherein said first group has a lower likelihood of tumor recurrence or spread than said second group, thereby determining a lower risk of tumor recurrence or spread in the first group of patients suffering from breast cancer.

Claims are further limited wherein the level of BAG-1 protein expression is determined by measuring the amount of BAG-1 protein product using an immunoassay; said level of BAG-1 protein expression is determined prior to lymph node involvement of said cancer; said level of BAG-1 protein expression is determined after lymph node involvement of said cancer; determining if said level of BAG-1 protein expression represents an overproduction that is above a reference level of BAG-1 expression, wherein said reference level of BAG-1 expression is determined by a histogram analysis; wherein said reference level of BAG-I expression is determined relative to a level of BAG-I expression in non-cancerous cells.

Turner et al. teach determining BAG-1 expression in benign breast epithelium (BBE), ductal carcinoma in situ (DCIS), and invasive carcinoma (IC) of the breast by immunohistochemistry using a monoclonal antibody on 87 cases containing IC or pure CDIS and BBE, wherein the patients had a median follow-up of 13 years. Turner et al. teach that the slides was rated on a scale of intensity and % distribution within the BBE, DCIS and IC components. Turner et al. teach that there is a statistic significant over expression of nuclear and cytoplasmic BAG1 in cancer patients compared to BBE patients. Turner et al. conclude that the subcellular location of BAG-1 may have prognostic importance with respect to survival of breast cancer patients.

The intended use for claims 35-37 and 53 (for determining the proper course of treatment for a patient suffering from breast cancer) is given no patentable weight.

The ductal carcinoma in situ (DCIS) is an early stage breast cancer (no lymph node is involved) and the invasive carcinoma has lymph node involvement. Therefore, all limitations are met.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 11-14, 16, 21-22, 24-27, 32-34, 36-37, 44 and 50-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) in view of Sano et al. (US patent NO. 5665539).

Claims 11, 13-14, 16, 21-22, 24-27, 32, 34, 36-37, 44 and 50-61 and their limitation are set forth above (see paragraph 5 above).

Claims 12 and 33 embody claims 11 and 32, wherein said immunoassay is an immuno-polymerase chain reaction (immuno-PCR) assay.

The teachings of Turner et al. are set forth above as they applied to claims 11, 13-14, 16, 21-22, 24-27, 32, 34, 36-37, 44 and 50-61.

Turner et al. do not teach the immuno-polymerase chain reaction (immuno-PCR) assay.

Sano et al. teach detection of a protein using immuno-PCR (see abstract).

Therefore it would have been prima facie obvious to one of ordinary skill in the art to combine the methods of Turner et al. and the detection techniques of Sano et al. and one would have been motivated to do so because these are useful and efficient methods of detection of a protein. Moreover, one of ordinary skill in the art would have a reasonable expectation of success of detecting BAG-1 using immuno-PCR because immuno-PCR was already a well-established method for protein detection at the time the invention was made.

8. Claims 11, 13-14, 16, 20-22, 24-27, 32, 34, 36-37, 44 and 50-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) in view of Sauter et al. (British Journal of Cancer, 1997, 76(4): 494-501).

Claims 11, 13-14, 16, 21-22, 24-27, 32, 34, 36-37, 44 and 50-61 and their limitation are set forth above (see paragraph 5 above).

Claims 20 and 62-66 embody claims 16, 25, 27, 34 and 54, wherein said level of BAG-1 protein is determined by measuring the level of BAG-1 protein in a sample of body fluid containing breast cancer cells.

The teachings of Turner et al. are set forth above as they applied to claims 11, 13-14, 16, 21-22, 24-27, 32, 34, 36-37, 44 and 50-61.

Turner et al. do not teach measuring the level of BAG-1 protein in a sample of body fluid containing breast cancer cells.

Sauter et al. teach that breast exudates fluid (nipple aspirate fluid) include breast cancer cells because breast cancer develops from ductal and lobular epithelium (see page 498, right column, 3rd paragraph).

Therefore it would have been prima facie obvious to one of ordinary skill in the art to combine the methods of Turner et al. and the teachings of Sauter et al. to detect BAG-1 in body fluid and one would have been motivated to do so because detection markers of breast cancer in body fluid is non-invasive as taught by Sauter et al. Moreover, one of ordinary skill in the art would have a reasonable expectation of success of detecting BAG-1 in body fluid because detection of a protein in body fluid is well known technique.

9. Claims 11, 13-14, 16, 21-27, 32, 34, 36-37, 44 and 50-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) in view of Takayama et al. (Cancer Res. 1998, 58: 3116-3131, IDS).

Claims 11, 13-14, 16, 21-22, 24-27, 32, 34, 36-37, 44 and 50-61 and their limitation are set forth above (see paragraph 5 above).

Claim 23 embody claim 21, wherein said reference level of BAG-I expression is determined relative to a level of BAG-I expression produced by in vitro cultured cells which produce BAG-I.

The teachings of Turner et al. are set forth above as they applied to claims 11, 13-14, 16, 21-22, 24-27, 32, 34, 36-37, 44 and 50-61.

Turner et al. do not teach the reference level of BAG-1 determined relative to a level of BAG-1 expressed in cultured cells.

Takayama et al. teach that BAG-1 protein expression levels (in ng per 50 μg total protein) were determined using immunoblot analysis for 67 human tumor cell lines including the National Cancer Institute screening panel of 60 human tumor cell lines, as well as an additional five human prostate cancer cell lines (see page 3117, right column, 1st paragraph).

Therefore it would have been prima facie obvious to one of ordinary skill in the art to combine the methods of Turner et al. and the teachings of Takayama et al. to use in vitro culture cells to determine the reference level for BAG-1 and one would have been motivated to do so because the reference level determined from the culture cells is stable and reproducible. Moreover, one of ordinary skill in the art would have a reasonable expectation of success of determining reference level using in vitro culture cells because it only involves routine technique and was taught by Takayama et al.

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang
Art Unit: 1643
Sept. 4, 2005

CHRISTOPHER YAEN
PATENT EXAMINER